**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST
VIRGINIA CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 2 CASES**	**JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF PAUL J. MICHAELS, M.D.

Plaintiffs in the above-captioned cases respectfully submit this Memorandum of Law in Opposition to the Defendants Motion to Exclude the Opinions and Testimony of Paul J. Michaels, M.D. and Memorandum in support thereof ("Def. Br.").

BACKGROUND AND QUALIFICATIONS

Dr. Paul Michaels is board certified by the American Board of Pathology in Anatomic Pathology, Clinical Pathology, and Cytopathology. Exhibit A – Expert Report of Paul J. Michaels, M.D. (*Childress et al. v. Ethicon et al.*) at p. 1; Exhibit B - Curriculum Vitae of Paul J. Michaels, M.D. Dr. Michaels has a strong subspecialty focus in breast and gynecologic pathology, as well as cytopathology. Exhibit A at 1. He received his medical degree from the University of California, Los Angeles School of Medicine and completed his residency in anatomic and clinical pathology at Massachusetts General Hospital, an affiliate of Harvard Medical School of Medicine where he was a Clinical Fellow in Pathology and also where he completed his residency in Cytopathology. *Id.*

Dr. Michaels is presently the Laboratory Director for two separate Stat clinical

laboratories in the Austin area, both of which are affiliated with Clinical Pathology Laboratory/Sonic Healthcare USA, the third largest pathology company in the United States. *Id*. He is currently affiliated with Clinical Pathology Associates in Austin, Texas and has privileges at numerous medical centers. *Id*.

During Dr. Michaels' medical training, he was educated and trained on the tissue response to foreign bodies generally. Exhibit C – General Opinion Deposition of Dr. Michaels, 6/18/2016, at 14:21-15:2 ("Michaels Dep."). Moreover, before he was retained as an expert witness by the plaintiffs in this litigation, Dr. Michaels had previously analyzed approximately 24 explanted polypropylene pelvic mesh specimens and frequently analyzing explanted polypropylene sutures specimens to determine the extent to which the polypropylene material contributed to his pathological findings, including the tissue response, foreign body reaction, fibrotic response and *in vivo* degradation observed by him macroscopically and microscopically using the same histology methods employed by experts within the pathology field. *Id*. at 13:2-14:2; 14:4-17; 52:4-13; 53:9-54:2; 54:8-55:11.

As discussed in greater detail below, Dr. Michaels is amply qualified to offer general opinions and testimony concerning the propensity for (1) Ethicon's Prolene polypropylene mesh material to undergo *in vivo* degradation, (2) complications associated with the *in vivo* degradation process; (3) *in vivo* mesh contraction, shrinkage and deformation; and (3) the associated complications caused by Ethicon's Prolene polypropylene pelvic mesh devices, including inflammation, scarring, nerve entrapment, erosions, chronic pain and dyspareunia to name a few. Dr. Michaels' opinions are reliably based on a combination of:

1) His personal experience as a diagnostic anatomic pathologist;

2) His frequent interactions with clinical colleagues in the day to day management of

patients;

3) Past and ongoing extensive review of pertinent literature in the field;

4) Various internal Ethicon documents;

5) Peer-reviewed publications; and

6) Depositions of Ethicon's employees.

As such, Ethicon's motion to exclude the general opinion testimony of Dr. Michaels should be denied as he possesses the requisite qualifications to offer his general opinions which are based on reliable methodologies that he reliably applied to the facts of the case and under Fed. R. Evid. 702, *Daubert* and its progeny.

ARGUMENT

Plaintiffs incorporate by reference the standard of review for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at **1-3 (S.D.W. Va. July 8, 2014). As this Court has previously concluded,

> I "need not determine that the proffered expert testimony is irrefutable or certainly correct" — "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" . . . "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached."

Eghnayem v. Boston Sci. Corp., 57 F. Supp 3d 658, 669 (S.D.W. Va. 2014).

I. Dr. Michaels is sufficiently qualified as a board certified pathologist under Fed. R. Evid. 702, Daubert and its progeny to offer his general degradation opinions at trial.

Ethicon argues that "Dr. Michaels bases his opinions that Ethicon mesh products degrade in vivo on his general pathology experience." Ethicon erroneously suggests that Dr. Michaels' degradation opinions are based soley on his general pathology experience. Def. Br. at 4. But a

review of Dr. Michaels' expert report and his deposition testimony clearly reveals that Dr. Michaels bases his degradation opinions, in large part, on his thorough review of the peer-reviewed published literature, Ethicon's internal corporate documents and depositions of Ethicon's employees as well as his experience as a board certified clinical and anatomical pathologist and mesh-specific histological analyzing of explanted polypropylene pelvic mesh and suture specimens. See Exhibit A – Expert Report of Paul J. Michaels (*Childress et al. v. Ethicon et al.*) at pp 1-5, 6, 9, 18. See also Exhibit C – Michaels Dep. at 15:15-16:18; 20:12-21:1; 39:2-11; 39:21-40:17; 40:6-41:9; 48:9-49:10; 49:17-18; 52:4-12; 57:9-24; 60:14-20; 63:2-12; 64:9-65:10; 65:21-66:5; 72:15-18; 76:14-77:13; 82:5-19; 103:11-104:4.

Tellingly, in a separate section of its own brief just 4 pages after suggesting that Dr. Michaels' degradation opinions are solely based on his general pathology experience, Ethicon dedicates approximately 4 pages to criticizes some of the peer-reviewed degradation publication that Dr. Dr. Michaels' relied upon in formulating his opinions and nearly 3 additional pages to criticizing the internal Ethicon studies that Dr. Michaels also relies. The Defendants' own brief demonstrates that Dr. Michaels relied on more than just his general pathology experience and illustrates the lengths at which Ethicon will go to win an argument by unfairly mischaracterizing Dr. Michaels' opinions and the methodology employed by him in these cases. Compare Def. Br. at p. 4 to Def. Br. at pp. 8-12.

The reason the Defendants employ this unfair strategy is apparent: they cannot offer any legitimate basis to exclude Dr. Michaels' degradation opinions. In fact, Defendants do not seriously challenge Dr. Michaels' qualifications as a board certified clinical or anatomical pathologist. Instead, throughout their brief, the Defendants wholly misrepresent Dr. Michaels' opinions and testimony by using incomplete "snippets" of testimony and then engaging in an

exercise of "gotcha" in an effort to twist Dr. Michaels' testimony into a basis for exclusion rather than soundly challenging his well-founded and reliable opinions. Such efforts by Defendants must fail.

Nevertheless, this Court reminded the parties nearly two years ago when ruling that Dr. Iakovlev was qualified to offer similar degradation opinions:

> …throughout these MDLs, I have allowed numerous pathologists to testify regarding the properties of polypropylene mesh.

See Eghnayem v. Boston Scientific Corp., 57 F. Supp. 3d 658, *5–9 (S.D. W. Va. 2014), (c*iting Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *19–20 (S.D. W. Va. Sept. 29, 2014) (ruling that pathologist, Dr. Richard W. Trepeta, was qualified to offer general opinions concerning the properties of polypropylene mesh, including opinions related to mesh degradation, mesh shrinkage, and mesh migration); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 621 (S.D. W. Va. 2013) ("Bard argues that Dr. Klosterhalfen is not qualified to opine on causation, and that the basis for his opinions is unreliable. Dr. Klosterhalfen's very job as a pathologist qualifies him to opine on this issue [of causation]."), and Dr. Zheng in *Huskey v. Ethicon, Inc., 2:12-cv-05201, 2014 U.S. Dist. LEXIS 92317, 2014 WL 3362264, at *34 (S.D. W. Va. July 8, 2014)* (ruling that Dr. Zheng, [*54] a pathologist, is qualified "to tell the jury the clinical reasons why patients such as Mrs. Huskey require excision of [their mesh devices]")). *See also, Bellew v. Ethicon*, Inc. et al., The United States District Court, Southern District of West Virginia, MDL NO. 2327; 2:12-cv-22473 Charleston, WV, USA (March 5, 2015) at * 28 in which the Court adopts the same language from *Eghnayem. Carlson v. Boston Scientific Corp*., No. 2:12-cv-05762, at *51, *available at* 2015 WL 1931311 at *29 (S.D. W. Va. 2015) (finding pathologist, Dr. Trepeta, qualified to offer general opinions concerning mesh degradation, mesh shrinkage, and mesh migration); *Tyree v. Boston Scientific Corp.*, 54 F.

Supp. 3d 501, *15–19 (S.D. W. Va. 2014), (discussing Dr. Richard Trepeta); *Bellew v. Ethicon*, No. 2:13-cv-22473 (S.D. W. Va. Nov. 20, 2014) [Doc. #265] (permitting pathologist, Dr. Robboy, to offer opinions regarding mesh at issue in case based on his comparison to what he viewed as typical mesh explants based on his clinical experience).

Dr. Michaels has been practicing pathology for nearly two decades and has been board certified in clinical pathologist, anatomical pathologist and cytopathologist for more than a decade with a strong focus in gynecologic pathology. Exhibit A at 1; Exhibit B at 2-3. Prior to being retained as an expert in these cases, Dr. Michaels analyzed approximately 24 explanted polypropylene pelvic mesh devices and has analyzed several additional Ethicon mesh explants in the context of this litigation. He has far more mesh-specific experience than many of the expert pathologists designated by Ethicon in these cases, such as Dr. Longacre who only analyzed 6 mesh explants prior to her involvement in this litigation (See Exhibit D – Deposition of Dr. Terri Longacre, 12/19/14, at 45:3-8) or Dr. Stephen Factor who had never analyzed a single explanted mesh specimen before the Defendants retained him. See Exhibit E - Deposition of Dr. Factor, 11/27/2012 at 19:13-18.

Yet the Defendants argue that Dr. Michaels' testimony "demonstrates that his experience has not provided him with the specialized knowledge necessary to offer" his general opinions that Ethicon's mesh products degrade *in vivo*. Def. Bf. At 4. In support of this argument, Defendants incorrectly assert that Dr. Michaels' experience with reviewing 24 explanted polypropylene mesh devices prior to his involvement in this litigation was limited to his gross analysis only. Def. Br. at 5. However, Dr. Michaels testified that he analyzed these explanted polypropylene pelvic mesh specimens using both gross and **and** microscopic histology techniques:

Q: Prior to your retention in this case, can you tell me something about your

familiarity with pelvic mesh implants?

A: Well, as a pathologist, I've been exposed to these speciemens over the last several years. So I've grossly examined them, microscopically examined them, prior to being involved in this litigation….

Q: Has that been in your capacity as a pathologist associated with a hospital?

A: That's correct.

Q: And how many pelvic mesh explants have you as a pathologist analyzed prior to your retention in this litigation?

A: I would probably say somewhere around two dozen, maybe.

Q. Over what period of time?

A. Seven, eight years, maybe.

Exhibit C at 12:8-13:1.

Throughout the Defendants' brief, they attempt to paint an inaccurate picture of Dr. Michaels' opinions and the methodology employed by him. For example, the Defendants argue that Dr. Michaels' pre-litigation degradation opinions are limited to "his general belief" that polypropylene sutures degrade and are based on nothing more than "general discussions" he had in the past. Def. Br. at 4. Contrary to the Defendants' representation, Dr. Michaels testified that he learned that polypropylene sutures can undergo *in vivo* degradation from reading published literature. *Id*. at 52:4-12 .

Dr. Michaels further testified:

Q: What do you remember that you read that the polypropylene sutures degraded?

A: ….I don't remember reading about the biochemical consequences or mechanisms, just that it can.

From a pathologist's point of view with respect to recognizing changes in the tissue, because we not infrequently will see suture materials in all types of excisions.

Id. at 53:18-54:2.

Q: Prior to your work in this case, have you ever analyzed polypropylene sutures to determine the extent to which they may have degraded in the body?

A: I would say I haven't analyzed them with respect to extent, just known that it occurs – can occur after a period of time and will have seen suture materials microscopically, but not more than that.

Q: And those times that you've described, is that in connection with your work as pathologist?

A: Yes.

Id. at 54:8-19; 55:12-56:9.

As Dr. Michaels' deposition testimony illustrates, he is sufficiently qualified as a board certified pathologist with considerable mesh-specific experience to offer his general degradation opinions. *See, e.g.*, *Frankum v. Bos. Sci. Corp*., No. 2:12-CV-00904, 2015 WL 1976952, at *24 (S.D. W. Va. May 1, 2015) (finding that an anatomical and clinical pathologist is qualified to testify about pathology of mesh material despite an apparent lack of training in polymer science or testing of mesh products). As such, the Defendants' argument should be rejected.

II. Dr. Michaels' Degradation Opinions Are Reliable.

a. Dr. Michaels' opinions concerning degradation, embrittlement and loss of mechanical properties are reliable.

The Defendants argue that Dr. Michaels' opinions concerning degradation, embrittlement and loss of mechanical properties are unreliable because – according to them – Dr. Michaels did not perform various chemical testing generally conducted by polymer scientists such as Fourier transform infrared spectroscopy ("FTIR"), scanning electron microscopy ("SEM"), gel permeation chromatography, and tensile strength testing. This Court has routinely denied similarly motions by Ethicon and other mesh manufacturing defendants who have sought to exclude similar degradation opinions by various experts who likewise did

not conduct the types of chemical tests the Defendants argue is necessary here.

In *Edwards*, Ethicon made an identical argument when it sought to exclude Dr. Iakovlev. Edwards at *43. In denying Ethicon's motion, this Court held that "Dr. Iakovlev is a pathologist, not a materials scientist. He makes determinations by processing and analyzing explants from the human body….the process Dr. Iakovlev used to analyze the explant is the industry standard in pathology." Dr. Michaels is also pathologist, not a polymer scientists, and specializes in the pathological analyzes of explanted tissue and foreign bodies. Like Dr. Iakovlev, Dr. Michaels uses polarized light microscopy to identify foreign materials which is the industry standard in pathology.

In addition to his pathology experience, Dr. Michaels relied on the peer-reviewed publications and Ethicon's internal documents. Exhibit C – Michaels Dep. at 15:15-16:18; 20:12-21:1; 39:2-11; 39:21-40:17; 40:6-41:9; 48:9-49:10; 49:17-18; 52:4-12; 57:9-24; 60:14-20; 63:2-12; 64:9-65:10; 65:21-66:5; 72:15-18; 76:14-77:13; 82:5-19; 103:11-104:4. See also Exhibit A at pp 1-5, 6, 9, 18. Far from reaching conclusory or unsupported opinions, Dr. Michaels details his degradation opinions, supporting each such opinion with citations to published literature as well as internal Ethicon degradation testing.

In *Bellew v. Ethicon*, this Court allowed Dr. Elliot, an urogynecologist, to offer degradation opinions based on his clinical experience as and his extensive review of the scientific literature and internal Ethicon documents. Bellew * 23 (also holding that Dr. Klinge's opinions concerning mesh degradation, fraying and particle loss were reliable because "throughout both of these sections of his expert report, Dr. Klinge supports his opinions, at least in part, by citing to peer-reviewed, published literature" including the peer-reviewed publications by Costella and Clave which, among other publications, Dr. Michaels similarly relies on for his degradation opinions).

b. Dr. Michaels' opinions concerning degradation, embrittlement and loss of mechanical properties are reliably based on his knowledge, training and experience as well as his review of peer-reviewed publications.

The Defendants again blatantly misrepresent Dr. Michaels' deposition testimony when they argue "Dr. Michaels testified that his embrittlement opinion is based solely on his 'examination of the gross specimens in the past[.]'" Def. Br. at 5. A clear reading of Dr. Michaels' expert report and deposition transcript tells a different story.

As an initial matter, Dr. Michaels' expert report demonstrates that he relied on numerous peer-reviewed publications to reach his degradation opinions. See Exhibit A at 5 (Liebert 1976, Jongelbloed 1986, Mary 1998, Costello 2007, Clave 2010, Wood 2013). Dr. Michaels' expert report further demonstrates that he relied on a number of internal Ethicon documents including an internal studies conducted by Ethicon's pathologists in 1984 which shows that Ethicon's own pathologists, using the same histology methods employed by Dr. Michaels, concluded that the Prolene fibers degrade, become embrittled and crack after implanted in the human body over time. According to Ethicon's pathologist: "The cracked layer appeared blue in gross specimens and **blue dye particles** were evident in histological sections of the layer. **This would indicate that the layer is dyed PROLENE polymer and not an isolated protein coating on the strands."** Exhibit F (emphasis added) (ETH.MESH.15955462). See also Exhibit A at 5. See also Exhibit C – Michaels' Dep. at 15:15-16:18; 20:12-21:1; 39:2-11; 39:21-40:17; 40:6-41:9; 48:9-49:10; 49:17-18; 52:4-12; 57:9-24; 60:14-20; 63:2-12; 64:9-65:10; 65:21-66:5; 72:15-18; 76:14-77:13; 82:5-19; 103:11-104:4.

Thus, Dr. Michaels clearly relied on the peer-reviewed publications and internal Ethicon documents in reaching his conclusions concerning degradation, embrittlement and loss of

mechanical properties –methods this Court has previously determined are reliable. Additionally, Dr. Michaels also relies on his pre-litigation pathology experience as well as the histological analysis of mesh explant specimens he reviewed as an expert witness in this litigation using industry standards in his pathology field, such as histology staining and polarized light microscopy. As discussed above, this Court has previously found these methods to be reliable.

c. Dr. Michaels' Use of Polarized Light Microscopy Is Reliable.

The methodology used by Dr. Michaels to review the explant specimens for degradation has been recognized as the industry standard by this Court and has been utilized by Ethicon itself for nearly 40 years. Ethicon's claim that there is no scientific or medical evidence to support Dr. Michaels' opinions concerning degradation "bark" from explanted mesh *in vivo* is simply wrong. Dozens of peer-reviewed articles have demonstrated that polypropylene degrades in the body. In other words, Dr. Michaels is not alone in his scientific research and his opinions in this case regarding the fact that polypropylene, including Ethicon's Prolene, degrades are overwhelming supported by the medical literature. Dr. Michaels used "standard histopathology techniques" including light microscopy that has been recognized for decades as a reliable method for identifying synthetic foreign materials.

Under a *Daubert* analysis, the dispositive question here is not, as Ethicon posits, whether Dr. Michaels' **conclusions** of degradation "bark" have been previously published in the medical and scientific literature. Instead, the appropriate question is whether Dr. Iakovlev utilized a n established, reliable **methodology** when studying the explanted mesh samples and when arriving at his opinions. In previously rejecting this same argument from Ethicon, this Court has stressed that "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions

reached." *Eghnayem v. Boston Sci. Corp*., 57 F. Supp. 3d 658, 669 (S.D. W. Va. 2014).

This Court has already found that the same methodology used by Dr. Michaels by other pathology experts to detect degradation "bark" is reliable. See *Edwards* at 70. Incredibly, the methodology used by Dr. Michaels to review the specimens for degradation – H&E staining and polarized light – are the methodologies that have been utilized by Ethicon's own pathologists who – like Dr. Michaels - concluded that Prolene does indeed undergo in vivo surface degradation. Ex. A. at 8-9.

Because the methods and techniques utilized by Dr. Iakovlev are not new or novel; are widely accepted in the medical community; and, are well accepted in the peer-reviewed literature (and evidently, well accepted by Ethicon's own scientists well before the litigation began), his methodology is sound and his conclusions – conclusions that are consistent with those of Ethicon's scientists dating back 30 years – are therefore admissible.

d. The peer-reviewed publications strongly support Dr. Michaels' degradation opinions despite the Defendants' misrepresentations.

The Defendants waste a considerable amount of time arguing that Dr. Michaels' opinions are unreliable because – according to them – the peer-reviewed publications he relies upon don't actually support his opinions. Def. Br. at 8-11. This couldn't be further from the truth. Indeed, every researcher in each study concluded that polypropylene undergoes in vivo degradation overtime. Yet, despite this, the Defendants argue for an opposite conclusion. For example, the Defendants argue that:

- Costello (2007): While the study found that Bard's polypropylene mesh degraded, it showed that the Prolene Soft polypropylene mesh manufactured by Ethicon did not degrade. Defendants' argument in this regard is wholly disingenuous. In the Costello study, the Prolene Soft mesh was used only as a control. It was a pristine mesh that had not been implanted in a patient and, therefore, was not exposed to the *in vivo* environment. The Prolene Soft in the Costello study was used as a control to make sure the cleaning process to remove the tissue from the explanted Bard specimen to

demonstrate that the cleaning process itself would not cause damage (an artifact) on the explanted specimen which would be misinterpreted as degradation. While the Costello article provides strong evidence that polypropylene-based mesh devices are susceptible to in vivo degradation, it is wholly unreliable to rely on the Costello study – as the Defendants do – to suggest that Prolene Soft mesh does not undergo *in vivo* degradation overtime.

- Wood (2013): Defendants argue that the Wood article does not support Dr. Michaels' degradation because the study may not have analyzed Prolene and involved hernia mesh, not mesh used in the pelvic floor. Like the Costello article, the Wood study provides strong support that polypropylene-mesh degrades *in vivo*.

- Jongebloed (1986): The Defendants admit the researchers found that Ethicon's Prolene suture degraded. This study provides strong support that Ethicon's Prolene-based products under in vivo degradation. The Defendants, however, argue that because this publication involved "ocular" Prolene sutures, it degraded from exposure to ultraviolet radiation. This study which involves the same material used in Ethicon's mesh devices provides strong evidence that Prolene is susceptible to in vivo degradation. The study also provides important information on how to distinguish "protein" artifact from cracked and degraded Prolene – an issue suspiciously ignored by the Defendants.

- Mary (1998): In the Mary study, the researchers compared explanted Prolene sutures to explanted PVDF sutures and concluded that Ethicon's Prolene degraded more rapidly in vivo than the PVDF sutures. This peer-reviewed publication provides very strong evidence that Ethicon's Prolene products degrade in vivo. Incredibly, however, Ethicon argues that this study doesn't support Dr. Michaels' degradation opinions because – according to Ethicon – the methodology used by these researchers was unreliable.

- Liebert (1976): Finally, Ethicon argues that the Liebert study shows that antioxidants protect polypropylene from degradation. The Liebert study, however, demonstrates that inadequately protected polypropylene fibers will degrade in vivo.

The studies relied upon by Dr. Michaels provide strong support that polypropylene and Prolene specifically are susceptible to *in vivo* degradation overtime yet the Defendants somehow reach the opposite conclusion. As this Court has previously concluded, however:

> I "need not determine that the proffered expert testimony is irrefutable or certainly correct" — "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" . . . "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the

conclusions reached."

Eghnayem v. Boston Sci. Corp., 57 F. Supp 3d 658, 669 (S.D.W. Va. 2014).

e. **Dr. Michaels' degradation opinions are further supported by Ethicon's own intenral documents.**

Dr. Michaels also relies on numerous internal Ethicon documents which provide strong support for his degradation opinions and are consistent with the published research and his experience analyzing explanted polypropylene mesh and suture specimens. Like the section immediately above, the Defendants argue that "none of the documents he cites actually supports his opinions." Def. Br. at 11. Not surprisingly, the Defendants continue misstate and mischaracterize evidence in this case. For example, the Defendants cite to Dr. Jordi's deposition from 3 years ago to suggest that that Dr. Jordi conceded that a decrease in molecular weight of an explanted polypropylene specimen is required to prove degradation.

Faced with similarly misrepresentations in the past, Dr. Jordi submitted a rebuttal report wherein he stated that any attempt to suggest that he has "concluded [] in my report that no molecular weight change is equivalent to no degradation" would be "far from the truth." See e.g., Exhibit G - Jordi Rebuttal Report, 11/5/13, at 24.

As if this wasn't clear enough, Dr. Jordi further wrote that "the degradation by free radical attack is a surface phenomenon. The bulk of the polymer will not be cracked at least initially" but any suggestion that "molecular weight changes are required to prove degradation by free radical attack is illogical and misleading. Additionally, the environmental stress cracking mechanism does not require changes in the molecular weight." *Id.*

Thus, the internal Ethicon documents that Dr. Michaels relies on and which

consistently demonstrate that Ethicon's Prolene degrades *in vivo* are reliable even without molecular weight data. But disagreement with an expert's opinions is not grounds for exclusion under *Daubert*. *Edwards v. Ethicon,* 2014 U.S. Dist. Lexis 92316, 69-70 (S.D. W. Va. 2014).

f. **Dr. Iakovlev's Opinions That Degradation Causes Clinical Complications is Well Supported and Reliable.**

Ethicon next argues that even if its mesh does degrade, Dr. Michaels cannot correlate that degradation to any clinical complications. In attempting to justify their argument, Ethicon misrepresents the state of the record, the state of the medical and scientific literature, and Dr. Michaels' own training and expertise. Ethicon is either purposefully or carelessly ignorant of this Court's prior orders that have consistently permitted pathologist, like Dr. Michaels, to testify as to the matters that are the subject of this Motion.

Dr. Michaels is qualified, by virtue of his training and experience as a clinical and anatomical pathologist, to opine on the correlation between clinical complications and pathology review. Indeed, that is his everyday job. As this Court has previously noted in connection with a previous Ethicon *Daubert* challenge to another pathologists:

> A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information. Dr. Iakovlev testified that "[e]verything which is taken out of the human body or taken off a human body at the time of death comes for a pathology co-examination, so we have to correlate the devices with the changes in the body, and this is part of our training as pathologists." According to Ethicon's expert Dr. Zheng vaginal mesh "just represent[s] a kind of foreign body" for a pathologist to examine. "[A] pathologist typically deals with many kinds of foreign or medical device[s] removed or explanted from patients . . . . So overall TVT or mesh-related product is part of those medical devices removed and then submit [ted] to the pathology department. The[] pathologist has expertise to examine them[.]" [Ethicon's Expert Dep. at 46.] Dr. Zheng has also testified that pathologists can help diagnose clinical problems, including symptoms such as pain and bleeding.

Edwards at 68-69. Dr. Michaels' job requires him to have "frequent interactions with clinical colleagues in the day to day management of patients." Dr. Michaels testified that as a diagnostic clinical pathologist his:

> [M]ain purpose in reviewing these slides is to correlate my microscopic findings with the clinical indication for the surgical removal of mesh. And to generate a pathologic differential diagnosis with regards to what the clinical indications was for the surgery and with what I'm seeing histologically and to rule out other causes that could have influenced the patient's infection, or pain or dyspareunia, or whatever – erosions, whatever else could have influenced that.

Exhibit B – Michaels Dep. at 82:5-14.

Elaborating further, Dr. Michaels testified that his goal as a pathologist is to "evaluate the types of materials that I see pathologically and to correlate whatever histopathologic responses I'm seeing to whatever material with what's going on clinically." Thus, by virtue of his education, training and experience as a clinical pathologist, Dr. Michaels is qualified to testify about the correlation between explanted mesh pathology and clinical complications; the potential injuries to the female body from Ethicon's mesh; and the correlation between mesh and pain in patients.

According to Dr. Michaels:

> The clinical significance with respect to degradation is that once you're degrading a foreign body and it breaks apart, there's a greater surface area now that the foreign body that's in connection and in affiliation with the tissue. So that woul dincraswe the inflammatory response, because now you have new foreign antigens that are in, I guess, direct contact with the tissue.
>
> That would then increase the inflammatory response, and that increased inflammatory response would potentially or likely, given the severity of it, lead to additional damage to the remaining polypropylene or foreign material. And then that would then lead to more breakdown and more degradation, which would then turn into this, you know, basically a cyclical phenomenon where you have a feedback loop that's just constantly going, contributing, to greater amount of inflammation and scarring.

Exhibit B – Michaels Dep. at 58:9. Dr. Michaels testified that these pathological features would then correlate with other clinical symptoms. *Id*. at 59:19-60:3. Dr. Michaels cited to peer-reviewed publications in his expert report that support this opinion. See Exhibit A at 5 and 9

Any criticisms the Defendants' may have concerning Dr. Michaels' inability to specifically recall the name of any study he relied upon or disagreements Ethicon may have concerning Dr. Michaels' interpretation of the studies is mere fodder for cross examination. Because Dr. Michaels' opinions are reliable, Ethicon's motion in this regard must be denied.

III. Dr. Michaels' Opinions Regarding Contraction, Shrinkage, and Deformation of Ethicon Mesh Products Are Reliable.

Ethicon argues that Dr. Michaels should be precluded from offering opinions concerning mesh contraction, shrinkage, and deformation of Ethicon mesh products because he failed to follow the standard methodology used by pathologists for determine how a specimen is oriented in the human body. The Defendants argument fundamentally misunderstands Dr. Michaels' role as a diagnostic anatomical pathologist and also fails to recognize that Dr. Michaels' opinions are based on multiple sources, including his review of the published literature and his own experience. *Id*. at 39:21-40:17. Moreover, Dr. Michaels uses "standard histology techniques" when he analyzes mesh explant specimens and has been trained to specifically identify artifacts: "as a pathologist, you can identify when there are folds in the tissue as opposed to something that is occurring biologically or pathologically." *Id*. at 50:24-51:8.

But Dr. Michaels doesn't just rely on one source of his opinions: "[w]hen I form an opinion it's based on everything, it's not based on just one thing." Id. 49:17-18. This is why Dr. Michaels' also relies on peer-reviewed publications and cited dozens within his expert report that support his mesh-contraction, shrinkage, and deformation opinions. See Exhibit A at 3-5.

See also Exhibit H - Dr. Michaels' Reliance List. As Dr. Michaels testimony demonstrates, he considers both sides of a disputed issue. *Id*. 48:6-15. Dr. Michaels' mesh-contraction, shrinkage and deformation opinions are sufficiently reliable under Daubert and this Court has allowed "numerous pathologists to testify regarding the properties of polypropylene mesh." *Eghnayem*, 57 F. Supp. 3d 658, *5–9 (S.D. W. Va. 2014), (citations omitted).

IV. DR. MICHEALS' OPINIONS REGARDING THE COMPLICATIONS CAUSED BY ETHICON'S MESH DEVICES ARE RELIABLE.

The Defendants again mischaracterize Dr. Michaels' testimony by suggesting he does not understand mechanisms of inflammatory response. Def. Br. at 15. This is yet another example of Ethicon taking a short sentence out of context to mischaracterize Dr. Michaels' opinions. What Dr. Michaels actually said was: "I would say the mechanisms with regard to inflammation and pain is something that is extremely complex and not something that I, as a pathologist generally would report or describe. Simply correlating the fact that inflammation is known to be associated with pain and reporting whether that inflammation is present or not, but not with regards to the receptors and the cytokines that are produced and the feedback loops and cycles…." Id. at 98:14-23. Dr. Michaels explains in great detail the mechanism of action of inflammation (see 99:11-100:9) demonstrating his eminent qualifications to offer this reliable opinion.

The Defendants also argue that Dr. Michaels' opinions are unreliable because – according to the Defendants – Dr. Michaels' opinions are contradicted by the Hill publication.

Dr. Michaels testified that he considered the Hill article but articulated several reasons why he felt the Hill article provided little helpful data – weaknesses that the authors themselves recognize. Def. Br. – Exhibit DD, A. Hill, et al. *Histopathololgy of Excised Midurethra Sling Mesh,* 26 Int'l Urogynecology J. at 594-595.

In any event, this Court has ruled throughout the mesh MDLs that pathologists are qualified to offer opinions concerning complications caused by Ethicon's mesh products. For example, in Sanchez v. Ethicon, this Court denied Boston Scientific's similarly argued the pathologist, Dr. Trepeta, was not qualified to offer reliable opinions concerning mesh-related complications. This Court disagreed:

> Again, Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through "clinical and pathologic correlation." (*See id*. at 11:10-14). Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, [*53] or physician findings) and reach a pathologic diagnosis about a patient. (*See id*.). Dr. Trepeta applied this pathologic process in reaching his conclusions about the human clinical responses to polypropylene vaginal mesh. He examined fifty pathology samples from mesh removals and opines that he observed injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." (Trepeta General Report [Docket 86-1], at 2). He also compared medical literature to these observations and concluded that his pathological findings "are well described in the published literature." (*Id*.). Dr. Trepeta's understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response.[4] Therefore, I **DENY** BSC's motion on this point.

Sanchez at *52-53. As discussed in detail above, Dr. Michaels applied the identical methodology applied by Dr. Trepeta in reaching his opinions concerning the types of complications caused by Ethicon's mesh products.

V. Dr. Michaels' opinions that pain can be caused by nerve entrapment within the mesh pores or scar is reliable.

Similarly, Ethicon misrepresents the record to the Court when it asserts that Dr. Michaels cannot support his opinions that the distortion and entrapment of nerves in mesh material and scare causes pain. Def. Br. at 17. Not only is this opinion not "novel" as Ethicon asserts, Dr. Iakovlev cites to numerous peer-reviewed publications that support his opinions in this regard. See e.g., Exhibit A at 2-5. Furthermore, Dr. Michaels has provided actual proof in the form of pathology slides from explanted mesh that shows dispositive that Ethicon's mesh becomes encapsulated in scar tissue, deforms and entraps nerves within the mesh and mesh-scar complex. Dr. Michaels also relies on his review of the medical records and deposition testimony and correlates his pathological findings with the clinical indication for mesh removal which provides Dr. Michaels with additional objective evidence to support his opinions. Exhibit B – Michaels Dep. at 82:5-14. The fact that Ethicon has embellished its *Daubert* motion with conflicting opinions asserted by its own paid experts is of no import to this motion and is not a valid argument under Daubert for exclusion of these conflicting opinions.

VI. DR. MICHAELS WILL NOT OFFER OPINIONS CONCERNING ETHICON'S KNOWLEDGE, STATE OF MIND, AND CORPORATE CONDUCT.

The Defendants last argument is that Dr. Michaels should be precluded from offering opinions concerning Ethicon's knowledge, state of mine, and corporate conduct. The Plaintiffs recognize that this Court has ruled that expert witnesses cannot offer these types of opinions and Plaintiffs will abide by the Court rulings in this regard. However, Dr. Michaels relies on several Ethicon internal documents for other permissible purposes. For example, Dr. Michaels relies on several internal documents to support his opinions that Prolene degrades or that Ethicon's Prolene mesh devices contract, shrink, and deform. Thus, while Dr. Michaels relies on numerous Ethicon documents and employee depositions, Dr. Michaels will not offer opinions

concerning Ethicon's knowledge, state of mind, and corporate conduct.

CONCLUSION

Dr. Michaels is eminently qualified as a board certified diagnostic pathologist to offer his general opinions concerning the properties of mesh, including the propensity for Ethicon's Prolene mesh to degrade and to causing complications to patients as discussed in detail above. Moreover, Dr. Michaels' opinion are reliable and overwhelmingly supported by the published literature and Ethicon's own internal documents. As such, the Defendants' motion to exclude Dr. Michaels should be denied in its entirety.

Dated: August 8, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 8, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

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